

Exhibit “B”

From: [Anthony Tabasso](#)
To: [Jaime Velez](#)
Cc: [Bill Schmidt](#)
Subject: RE: Launch plan for post Warning Letter response activities
Date: Monday, March 9, 2020 12:54:45 PM
Attachments: [image001.png](#)

Good afternoon, Jaime. The biggest challenge for us at this point is going to be seating. I will work through this with Steve and come up with a plan. Laptops will be here for everyone next Monday.

Dr. Thuene should be up and running by now

From: Jaime Velez <Jaime.Velez@oqsie.com>
Sent: Monday, March 9, 2020 1:53 AM
To: Anthony Tabasso <ATabasso@kvtech.com>
Cc: Bill Schmidt <Bill.Schmidt@oqsie.com>
Subject: Launch plan for post Warning Letter response activities

Hi Anthony,
Hope you had a good weekend.

Attached you will find the plan for the next four weeks or so. Need your approval to proceed to deploy the consultants as captured on page 4, i.e. add 9 consultants to the team currently deployed by March 16th. Steve Lynn will continue to play the role of Advisor on an ad-hoc basis.

For budget purposes. bill rates will be as follows, per hour:

Program Manager - [REDACTED]

Laboratory, Data Integrity, and Training SMEs - [REDACTED]

Observation 2 Team Leaders - [REDACTED] on average, i.e. some will be higher and some lower

Observation 2 Team Members - [REDACTED] to [REDACTED] for this initial group, we will update the range once we have clarity on resource requirements beyond this initial group, expect the range to likely go to [REDACTED] to [REDACTED]

Please let me know if you have any questions, I can talk between 10:30 am and 1:30 pm ET, traveling the rest of the day but can communicate via email. Feel free to call either Bill or I as your calendar permits.

Thanks,

Jaime

Jaime Velez
Co-Founder
Operations & Quality Systems Improvement Experts (OQSIE)

+1 267.664.9986 (mobile)
Jaime.Velez@oqsie.com

www.linkedin.com/pub/jaime-velez/4/797/b2b/

www.oqsie.com



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Operations & Quality Systems Improvement Experts (OQSIE)

**Initial plan to support KVK Tech to
meet commitments captured in
warning letter response**

OQSIE

03/08/2020



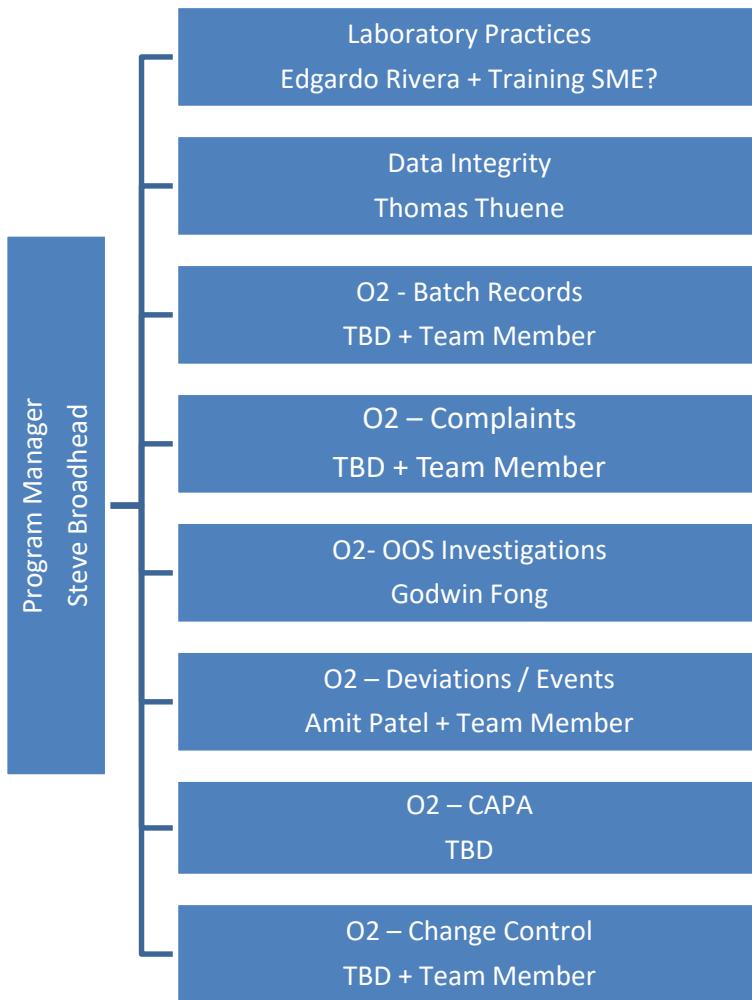
❖ Table of Contents

- Executive Summary
- OQSIE Team Structure
- Observation 1 Plan
- Observation 2 Plan
- Observation 3 Plan

Executive Summary

- Now that the Warning Letter response has been issued, OQSIE will collaborate with KVK Tech to ensure all commitments made in the response letter are met on a timely basis.
- High level plan of attack is as follows:
 - Observations 1 and 3: first conduct assessments committed; then develop action plans to remediate any gaps identified in the assessment; then execute the defined remediation plan with a combination of KVK Tech and external resources
 - By March 9th, OQSIE will have deployed consultants to conduct assessments for Observations 1 and 3
 - Observation 2: the extensive work of prospective and retrospective reviews will be broken down by topic, small teams of SMEs will be deployed for each topic with the objective of completing this work within 12 months (target timeframe will dictate the size of the teams)
 - Teams will be deployed for: 1) Batch Records, 2) Complaints, 3) OOS Investigations, 4) Deviations & Events, 5) CAPA, and 6) Change Control
 - By March 16th, OQSIE will deploy the first two team members for most of the teams associated with Observation 2, this group will organize activities to ensure rapid and effective integration of the balance of the team members
 - By April 6th OQSIE will have deployed the balance of the team members

❖ Proposed OQSIE Team Structure – by March 16th



❖ Approach & Timeline – Observation 1

			
Key Activities	<ul style="list-style-type: none"> • Comprehensive review of laboratory operations • Review training effectiveness • CAPA and MOA reviews to be incorporated into Observation 2 activities 	<ul style="list-style-type: none"> • Develop plan to address each gap identified in assessment of laboratory operations • If necessary, develop plan to address issues with training effectiveness • Define resource plan 	<ul style="list-style-type: none"> • TBD
Key Deliverables	<ul style="list-style-type: none"> • Assessment report • Gaps to be remediated 	<ul style="list-style-type: none"> • Remediation plans • Resource plan 	<ul style="list-style-type: none"> • TDB
OQSIE Resources*	<ul style="list-style-type: none"> • One Senior Laboratory SME <ul style="list-style-type: none"> • Edgardo Rivera • Training SME* 	<ul style="list-style-type: none"> • One Senior Laboratory SME <ul style="list-style-type: none"> • Edgardo Rivera • Training SME (if necessary) 	<ul style="list-style-type: none"> • TDB
Timing*	<ul style="list-style-type: none"> • Approximately 20 days 	<ul style="list-style-type: none"> • Approximately 10 days 	<ul style="list-style-type: none"> • TBD

* To be confirmed during week of March 9th

❖ Approach & Timeline – Observation 2

	Step 1 Organize	Step 2 Ramp Up Review Rate	Step 3 Stabilize Review Rate
Key Activities	<ul style="list-style-type: none"> Initial protocol execution If necessary, adjust protocol Develop review templates for each document type Define information flow Define governance and escalation process 	<ul style="list-style-type: none"> On-board team members Deploy progress tracking and performance management system Evolve information flow, and governance and escalation processes 	<ul style="list-style-type: none"> Team members delivering reviews at expected rates Effective governance and escalation process in place
Key Deliverables	<ul style="list-style-type: none"> Finalized protocols, templates and procedures Determine resource requirements for each team 	<ul style="list-style-type: none"> Confirm resource requirements Implement performance management system 	<ul style="list-style-type: none"> Reviews delivered at expected rates
OQSIE Resources*	<ul style="list-style-type: none"> One team leader for each document type (6) One team member for each document type (6) 	<ul style="list-style-type: none"> One team leader per doc type Multiple team members per doc type (preliminary estimates in next page) 	<ul style="list-style-type: none"> One team leader per doc type Multiple team members per doc type (preliminary estimates in next page)
Timing*	<ul style="list-style-type: none"> Approximately 10 days 	<ul style="list-style-type: none"> Approximately 10 days 	<ul style="list-style-type: none"> Approximately 11 months

* To be confirmed during week of March 9th

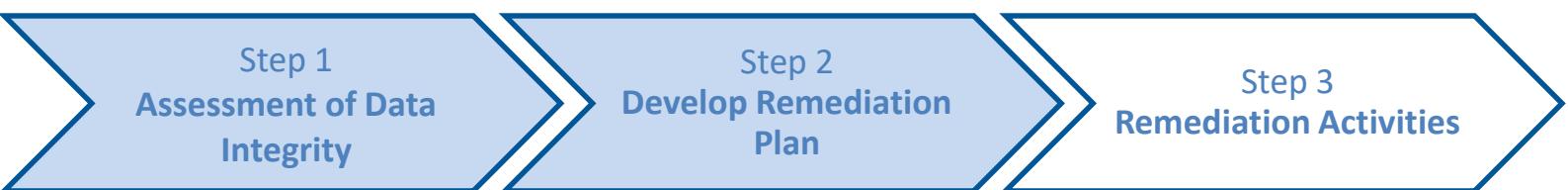
❖ Observation 2 – Preliminary Resource Estimates

Document / Topic	# reviews in scope (2016 to 2019) + Prospective	# of Consultants*
Batch Records	1,753 + 672	5 to 10.1
Complaints	935 + 381	3 to 5.5
OOS Investigations	155 + 28	0.9
Deviations / Events	1,245 + 571	4 to 7.6
CAPA	392 + 115	1 to 2.1
Change Control	2,237 + 553	6 to 11.6
Totals	6,717 + 2,320	20 to 38

* Estimates based on three key assumptions to be confirmed by March 31st:

- 1) All retrospective reviews to be completed within 12 months (240 work days)
- 2) Each review and associated documentation takes between half to one man-day to complete on average
- 3) Volume of prospective reviews in the next 12 months will be similar to that of 2019

❖ Approach & Timeline – Observation 3

			
Key Activities	Step 1 Assessment of Data Integrity	Step 2 Develop Remediation Plan	Step 3 Remediation Activities
	<ul style="list-style-type: none"> Initial assessment of potential Data Integrity practices Determine if forensic analysis is required 	<ul style="list-style-type: none"> Develop plan to address each gap identified in assessment If necessary, develop plan to conduct forensic analysis Define resource plan 	<ul style="list-style-type: none"> TBD
Key Deliverables	<ul style="list-style-type: none"> Assessment report Gaps to be remediated 	<ul style="list-style-type: none"> Remediation plans Resource plan 	<ul style="list-style-type: none"> TDB
OQSIE Resources*	<ul style="list-style-type: none"> One Data Integrity SME <ul style="list-style-type: none"> Thomas Thuene 	<ul style="list-style-type: none"> One Data Integrity SME <ul style="list-style-type: none"> Thomas Thuene 	<ul style="list-style-type: none"> TDB
Timing*	<ul style="list-style-type: none"> Approximately 10 days 	<ul style="list-style-type: none"> Approximately 10 days 	<ul style="list-style-type: none"> TBD

* To be confirmed during week of March 9th